



**Report of the Consensus Meeting
*Using New Guidelines to Help Prevent Cervical
Cancer and HPV Disease in Women***

**Hosted by
Association of Reproductive Health Professionals**

September 20, 2013

Denver, CO

Introduction

Advances in cervical cancer screening in the United States have resulted in significant declines in cervical cancer morbidity and mortality. Many health care providers remain unclear about how to navigate recently updated recommendations while providing optimal care. This year, new guidelines for primary screening for cervical cancer were jointly issued by the U.S. Preventive Services Task Force (USPSTF) and a consortium of the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society of Clinical Pathologists (ASCP). The preventive care initiatives within the Affordable Care Act (ACA) have the potential to have a positive effect on the prevention of cervical cancer, but many providers remain unclear about its implementation and its impact on clinical care. Educational outreach to providers, patients, and insurers is urgently needed to address the confusion about the new cervical cancer guidelines.

The Association of Reproductive Health Professionals (ARHP) convened a consensus meeting with 10 leading clinical and policy experts on cervical cancer prevention. This meeting took place on September 20, 2013, in conjunction with ARHP's annual meeting, *Reproductive Health 2013*, in Denver, Colorado. The goal of the meeting was to develop expert consensus on key issues surrounding the prevention of HPV infection and cervical cancer that remain unclear or problematic in clinical care and health policy within the provisions of the ACA.

The issues covered included the provisions of ACA that affect screening for cervical cancer, the latest guidelines and recommendations for the prevention of cervical cancer, screening for HPV infection and cervical cancer (i.e., Pap testing), and the issues around cervical cancer screening that affect Community Health Centers and other clinical settings.

The meeting format was that of a consensus meeting, with extensive discussion of each topic. The four discussion topics were:

1. ACA policy overview
2. Ensuring the latest evidence-based clinical education and training for primary care providers on the latest HPV and cervical cancer prevention recommendations and guidelines
3. Use of "gold standard" HPV and cervical cancer screening tools

4. Implementing HPV and cervical cancer screenings in a variety of clinical settings (including Community Health Centers), given health reform and related policy changes

Each section included an expert overview of the topic, a discussion of practice gaps, and participants' suggestions for ways to address and overcome barriers.

The meeting was supported through an independent educational grant from Roche Pharmaceuticals.

Key Themes and Messages

- The latest HPV and cervical cancer prevention recommendations and guidelines comprise a major paradigm shift in approaches to screening due to a newer understanding of the natural history of HPV and the development of cervical cancer when HPV infection persists.
- Health care providers are in need of clinical training opportunities about the new guidelines for HPV and cervical cancer screening and management.
- Implementation of ACA is likely to increase access to cervical cancer screening services, including co-testing, for many low-income, underserved women.
- Significant gaps in knowledge exist around the areas of timing of Pap testing, co-testing with HPV, follow-up testing, and concerns over persistence of HPV.
- Providers, members of the administrative office team (including front desk staff), patients, and insurers all need education around these topics.
- Educational efforts should provide a clear, consistent message across audiences.
- Education for both providers and patients should involve repeated messages and multiple modalities.
- Patient educational efforts need to consider health literacy issues, multilingual needs, and multicultural needs.
- Safety net providers, including Federally Qualified Health Centers (FQHCs), Community Health Centers (CHC), Community Migrant and Rural Health Centers, and Family Planning Centers (FPCs) face additional challenges related to their funding sources and mission of serving low-income and hard-to-reach clients.
- Cervical cancer prevention is a challenging and complex topic.

Key Issues

1. Health Reform: ACA Policy Overview

Introduction

Specific provisions of ACA are intended to increase access to cervical cancer screening services for many low-income, underserved women. The ACA covers Pap tests, HPV vaccines, and HPV tests without copays as part of preventive care for women. Specifically, co-testing with HPV testing (i.e., testing for high-risk HPV DNA in women age ≥ 30 years) plus Pap testing is part of the women's preventive services guidelines (see www.hrsa.gov/womensguidelines). The ACA will expand the role of the National Breast and Cervical Cancer Early Detection Program (NBCCEDP) in connecting women to services while trimming back screening, diagnosis, and treatment services. Women at 0–138% of the federal poverty level should be able to transition to comprehensive health coverage under Medicaid or subsidized policies offered through the health care marketplace.

Key Practice Gaps

- Medical personnel are not consistently following current recommended Pap testing guidelines (i.e., generally screening every 3 years, not annually).
- Professional organizations and state recommendations for Pap testing may need updating to match the national guidelines.
- Many women have relied on annual Pap testing as their only contact with the medical system; these women will need education about the new testing guidelines and need to understand why they should continue to see providers even when they do not need a Pap test.
- Health literacy is a particular challenge when educating patients about topics related to the prevention of HPV infection and cervical cancer.

Additional Challenges

- Many women will continue to lack health insurance, even with changes provided by the ACA. These women include many of the working poor in states where Medicaid is not being expanded under the ACA, as well as undocumented women.
- Many new patients will have access to co-testing for the first time. This will create a reservoir of patients who will also need follow-up diagnostic testing (e.g., colposcopy) for the first time.

- Follow-up testing will fall under deductibles and/or co-pays (not routine covered care), which may mean that fewer patients will follow through with recommended care.
- Because there are a limited number of providers available in rural states and rural areas, women may choose not to travel long distances for preventive care they don't view as critical, including HPV and Pap testing.
- Anti-ACA advertising and general confusion about the new insurance plans compound the already existing problem of women's poor understanding about HPV and cervical cancer screening.
- Under the ACA model of the "medical home," practices are expected to have staff for coordinated care for a large number of new patients.

Ways to Address and Overcome Barriers

- Provide up-to-date information for providers and staff, including gate-keepers like receptionists.
 - Use the ACA as a "hook": "What do you need to know about cervical cancer screening now that ACA is starting?"
 - Provide one consistent primary message.
- Providers should use a written script with patients that highlight the key points about why the recommendations for cervical screening have changed, so that the message is clear and consistent for every patient.
- Devise a patient-focused mobile device app for providers and patients to increase understanding of HPV and cervical cancer screening.
- Create social media campaigns for both patient and provider education.
- Target messages to different groups, taking into account cultural differences, rather than creating one educational approach for all patients.

2. Ensuring the latest evidence-based clinical education and training for primary care providers on the latest HPV and cervical cancer prevention recommendations and guidelines, including related patient education issues

Introduction

The latest HPV and cervical cancer prevention recommendations and guidelines comprise a major paradigm shift. There are new guidelines for screening and management, but many providers are unclear about how to navigate through these.

Key Practice Gaps

- Many providers may not be aware of the new guidelines.
- Many providers have resisted adopting new guidelines. Some of the reluctance to change is not resistance to new ideas; it is occurring because practices are overstretched.
- There is considerable over-screening of low-risk populations.
- The insurance companies that develop payment policies have not been included as participants in the discussion about improving care.
- Patients lack knowledge about new guidelines. Many remember only the “annual Pap smear” and feel more comfortable continuing with it and even request this for their daughters. Surveys in 2008 and 2012 asked how many women are comfortable with screening intervals; in both surveys, only about 25% of patients felt comfortable the change, and no progress was seen during those four years.
- Providers are likely to have many new patients (under the ACA) who are new to a practice where there is not an established medical history on file. Turbulence or “churning” is expected in the insurance marketplace (i.e., switching from provider to provider as patients move from one insurer to another or from Medicaid to private insurance and back). Providers will need to give patients guidance about what to do and how to obtain testing so that they will be able to bring these results to a new provider in the future. In addition, the portability of Pap test results from provider to provider is a real issue. Often, Pap tests are repeated because the new provider does not have a record of previous results.
- Quality measures are set by public and private agencies to measure clinics’ performance. For example, the Health Resources and Services Administration, which provides grant funding to rural and community health centers, sets its goal for cervical cancer screening by health centers at 93% to align with Healthy People 2020. Performance data indicate that the screening rate is approximately 70–85% for high-performing health centers.

Additional Challenges

- Providers are concerned about whether patients will come back as scheduled at three years or five years if they move away from annual testing. In addition, providers want patients to come back annually for well-woman exams or screening for sexually transmitted infections, and that is now tied to the Pap test in many patients’ minds.

- Not all providers who provide cervical cancer screening do follow-up testing such as colposcopy. This means that their patients must see other providers for follow-up, an additional burden of time and money.
- Providers are concerned that patients think they are recommending fewer Pap tests in order to save money.
- Providers often have only a short time to provide care and education with each patient that they see.
- Due to the emphasis on establishing a “medical home,” more women are likely to be seen in the future by a primary care provider, rather than by an obstetrician/gynecologist or other specialist, for initial screening.

Ways to Address and Overcome Barriers

- Clinical education activities and other outreach to providers should emphasize the newer understanding of the natural history of HPV and the development of cervical cancer, as well as the evidence that supports widened screening intervals and co-testing of women age 30 and older.
- Create a consistent message about what testing providers should do every year, and why, broken down by age group, for providers, patients, and front desk staff.
- Include a little information about cervical cancer screening during the well-women exam each year, so that a consistent message is repeated as part of a “checklist” of information specific to each age group. Other topics to be covered include, for example, obesity, diabetes, depression, etc.
- Patient hand-outs, such as patient information sheets, that emphasize main points can be very useful and effective.
- Use many modalities to repeat information for patients, including reminder systems, text messages, Web site information.
- Laboratories have changed related to reimbursements for cervical cancer screening; some won’t run a co-test on a woman under a certain age without a medical director override to reduce the chance a provider would test a woman under age 30 when it is not appropriate.
- Share real-world data available about the loss of patients to follow-up with a switch to less frequent testing. The current guidelines were based on existing Kaiser and European data sets.

- Work with the Centers for Disease Control and Prevention (CDC) and ASCCP to create one combined voice; the ASCCP already has an app for cervical cancer screening.
- UpToDate is another standard clinical resource. (www.uptodate.com; UpToDate patient info on Cervical Cancer Screening recommends Pap every three years, HPV co-test if 30 years or older at www.uptodate.com/contents/cervical-cancer-screening-beyond-the-basics?detectedLanguage=en&source=search_result&search=HPV&selectedTitle=5%7E15&provider=noProvider)
- Stress the increased benefit and reduction in harm to both providers and patients.
- Electronic medical record vendors could build in guideline objects and templates to increase provider adherence.
- If a practitioner has enough time to explain cervical cancer screening with a patient, this reduces patient resistance to switching to fewer Pap tests.
- Insurance companies that develop payment policies could be big advocates if they have a financial incentive to follow those guidelines. Their medical directors need education; they are generally not reproductive health experts. Payment guides clinicians' behaviors.

3. Use of "gold standard" HPV and cervical cancer screening tools

Introduction

Guidelines recommending HPV screening, along with Pap testing, of all women age 30 and older, were first approved in 2003, and genotyping for HPV 16 and 18 was approved in 2009. There are now four tests that are approved by the U.S. Food and Drug Administration (FDA) for HPV testing. Three of these tests are for HPV DNA, and one is for HPV RNA. There are no FDA indications for the use of these tests to detect low-risk HPV types, because these types are not relevant for cancer prevention strategies. Testing is more complicated than finding a single positive result, however. The primary concern for the development of cervical pre-cancer and cancer is a persistence of high-risk HPV types. HPV testing in screening starts at age 30, because that is the age when a positive test for HPV more likely represents persistent infection. The guidelines for follow up add additional complexity (for a summary of the guidelines, please see ARHP's *Managing HPV: A New Era in Patient Care Quick Reference Guide* which is posted at www.arhp.org/QRG).

Practice Gaps

- Providers may be confused about which tests to use and when to offer them.
- Most clinicians don't know which type of test is conducted because they don't choose a specific laboratory test when they order a high-risk HPV screen. The test is chosen and validated the by laboratory used by the provider.
- Many practitioners may not fully understand the concept of the risk of persistence of high-risk HPV types, as opposed to the transient nature of HPV infection for most women.
- Most immunocompetent women will clear up to 90% of HPV infections within two years. Long-term persistence of high-risk HPV is necessary for the maintenance and progression of high-grade lesions. New screening guidelines and management are meant to decrease over-response to transient HPV infections and neoplasia in young women, decrease the over-screening of low-risk women, and detect HPV that may be persistent in women age 30 and older. Patients need knowledge about HPV persistence and what it means.
- Some providers also need explanations of the presence of HPV infection versus the presence of a lesion (dysplasia).
- Some providers state, "These are only guidelines. I do what I think is best for the patient." They may choose to continue with annual Pap tests, for example, because they feel more comfortable with the older approach. Additional education about why following the guidelines is important may help change behavior.

Additional Challenges

- The FDA-approved HPV tests are different and have different levels of sensitivity. Clinicians should be aware of which test is being used and whether they have access to genotyping.
- Research tests that are not FDA approved may be in use in certain settings.
- The Pap test can identify the presence of abnormal cellular changes and is less sensitive, but more specific, than the HPV test.
- Although the HPV test is more sensitive than the Pap test, at this time the HPV test is not FDA approved as a stand-alone test. The recommendation and FDA approval is for co-testing by Pap and HPV testing.
- Multi-year funding is critical for advocacy and education groups focused on cervical prevention education, but most funding organizations have not been making cervical

cancer a priority, and much of the current funding is done through industry via one-year grants.

Ways to Address and Overcome Barriers

- It is important to reach young providers who may influence change within their settings to change to meet the new guidelines. It will be important to include pediatricians because they are the ones vaccinating for HPV, an important aspect of preventing cervical cancer. Their message is that adolescent girls do not need Pap tests.
- The initial message should focus on co-testing and should include an explanation of the value of identifying women who are at risk for disease missed by the Pap or who are at risk for the development of neoplasia if there is persistence of HPV infection.
- Persistence of high-risk HPV should be an important part of educational programs that discuss HPV testing. The messages should also include historical perspectives including changes seen on colposcopy, the role of HPV in the development of cervical cancer, the role of HPV vaccination, and the fact that the current guidelines help to reduce over-testing as well as patients' anxiety, time, and cost. The risk of cervical cancer should be put into proper perspective for patients. In addition, the changes should be discussed in terms of evidence-based medicine.
- Wonderful materials exist; these should be utilized to provide clear, consistent, repeated messages to patients and providers.
- Payers and insurers need to be educated in addition to providers and patients.
- Acknowledge to patients that today's guidelines may change, even in the near future. Although this is not comforting, it is reality. Stress that cervical cancer and HPV testing are areas where knowledge keeps expanding and science keeps getting stronger.
- Find out what European countries are doing to overcome provider barriers to change. Some of these countries have already implemented similar guidelines.
- Additional examples of ways to provide appropriate education around this topic include ARHP *Clinical Minutes*, public service announcements, case studies, using cervical cancer survivors as advocates, social media, and apps for mobile devices.
- Make co-testing a National Committee for Quality Assurance (NCQA) Healthcare Effectiveness Data and Information Set (HEDIS) measure.

[For the 2014 reporting year, NCQA added HPV co-testing as an appropriate screening method for women ages 30–64 and the hybrid reporting method for

commercial plans. This revised measure assesses the percentage of women 21–64 years of age who were screened for cervical cancer using either of the following criteria:

- *Women age 21–64 who had cervical cytology performed every 3 years.*
- *Women age 30–64 who had cytology and/or HPV co-testing performed every 5 years]*

4. Implementing HPV and cervical cancer screening in a variety of clinical settings given health reform and related policy changes

Introduction

Safety net providers, including Federally Qualified Health Centers (FQHCs), Community Health Centers (CHC), Community Migrant and Rural Health Centers, and Family Planning Centers are in position to become medical health homes. CHCs and FQHCs are expected to be the major players under the ACA, and CHC capacity is projected to double by 2019. Their role in providing women’s health care will grow significantly, especially for low-income women.

Practice Gaps

- Health professionals in these clinical centers also need education about changes in recommendations for HPV testing and cervical cancer screening, including co-testing and changes in the schedule for Pap tests.
- Cervical cancer and HPV experts have a knowledge gap in understanding the struggles and other issues of an uninsured population.
- Information about HPV vaccination is needed.
- Uninsured women are less likely than insured women to receive Pap testing (67% vs. 83%). However, uninsured women in CHCs are 22% more likely than their counterparts in private practice to receive Pap tests, 17% more likely to receive clinical breast exams, and 16% more likely to receive management.
- Staff recruitment and retention is often a challenge and impacts educational efforts.

Additional Challenges

- These centers must balance depth of care for any particular population with the ability to respond to the full range of primary care needs.

- Aggressive cost containment has led to long wait times; smaller formularies; volume purchasing; lack of ability to offer latest equipment, tests, and techniques; lack of staffing depth; less specialty care; fewer locations; and shorter hours.
- There may be limitations on the referral or availability of in-house specialty care.
- Some centers may place so much value on social justice and fairness that if they can't afford testing for everyone, then they won't provide it to anyone. Even if insured patients could pay for it, the uninsured can't. How can we make this available to everyone?
- There is concern about the amounts and timeliness of Medicaid payment for patient screening. More patients will be eligible for Medicaid in some states, as opposed to being seen under a grant. These centers are likely to face capacity issues as a flood of newly insured clients seek providers and medical homes.
- It is unknown whether low-resource settings will invest in prevention efforts through vaccination as opposed to testing (lower costs).

Ways to Address and Overcome Barriers

- Provide cost-benefit analysis about HPV co-testing.
- Could these centers have a sexual and reproductive health specialist (e.g., a nurse) co-located in CHC?
- If women's health services move in house into CHCs, this would improve overall care, screening and co-testing rates, follow-up, etc.
- Could Title X clinics lease their empty rooms to other care providers? CHCs will have capacity problems, so maybe the less busy family planning clinics could offer to co-locate prenatal care, well-woman care, and contraceptive care and create an environment of easy internal referral that would work to everyone's advantage.
- The health provider community needs to work on policies around vaccination to make it simpler to provide HPV vaccination.
- Could volume purchasing save money—for example, a statewide laboratory contract for Pap tests from a single source or a regional contract for HPV testing (modeled after the national Infertility Prevention Project/Chlamydia project)?
- If AHRQ adds a quality measure for HPV testing, then clinics would follow that measure; the centers' baseline value should be assessed.
- Patients served by CHC are the populations that would be well served by co-testing. We need to generate excitement and awareness of this opportunity for CHC.

- We need to create a consistent message before calling in reporters and media coverage.
- If we increase the public's knowledge about access to free HPV vaccine, this would raise awareness about the HPV issue.
- More training around HPV vaccination is needed, including an emphasis that it is not an issue of discussing sex.
- One of the toughest groups to address is 18- to 20-year-olds who have never made health care decisions for themselves before.
- We need to address multilingual needs and issues of health literacy, including the need for more visually based information for patients.
- We could approach health plans to make cervical cancer screening recommendations part of their guidelines.
- Create partnerships with ARHP to maximize efficiencies and resources.

Summary

There is a significant practice gap in the implementation of the new cervical cancer prevention guidelines, in addition to confusion about how the ACA will affect their implementation. These 10 leading clinical and policy experts on HPV and cervical cancer prevention identified specific gaps in understanding the ACA, implementing new guidelines, and the use of gold standard HPV and cervical cancer diagnostic tools. They also explained some of the problems that are unique to certain clinical settings, such as CHC. The group brainstormed many options for overcoming barriers that affect providers and/or patients in each of the areas and identified insurers as another group that should be included in education outreach. They concluded with a plea that this outreach is needed urgently to address the current confusion over not only what is needed for best practice in screening for cervical cancer but also how best to implement the guidelines in diverse practice settings.

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Appendix A

Consensus Meeting Agenda

Friday, September 20, 2013

Denver, CO

- 1:30 Welcome, Introductions (Geoffrey Knox, Facilitator)
Goals of Meeting, Review of Agenda (Nancy Berman, MSN, APRN, BC)
- 1:45 – 2:25 ACA Policy Overview, Q&A
- 2:25 – 3:25 Ensuring the latest evidence-based clinical education and training for primary care providers on the latest HPV and cervical cancer prevention recommendations and guidelines (Nancy Berman, MSN, APRN, BC)
- Practice Gaps
 - Ways to Address and Overcome Barriers
- 3:25 – 3:35 Break
- 3:35 – 4:35 Use of “gold standard” HPV and cervical cancer diagnostic tools (Versie Johnson-Mallard, PhD, WHNP-BC)
- Practice Gaps
 - Ways to Address and Overcome Barriers
- 4:35 - 4:45 Break
- 4:45 – 5:45 Implementing HPV and cervical cancer screenings in a variety of clinical settings (e.g., Community Health Centers), given health reform and related policy changes (Mary “Chris” Knutson, PHNC, RN-C)
- Practice Gaps
 - Ways to Address and Overcome Barriers
- 5:45 – 5:55 Break

5:55 – 6:20	Summary of Practice Gaps and Issues in HPV/Cervical Cancer Screening and Action Steps (Geoffrey Knox, Facilitator)
6:20 – 6:30	Next Steps (Geoffrey Knox, Facilitator)
6:30	Adjourn

Appendix B

Questions for Discussion

Ensuring the latest evidence-based clinical education and training for primary care providers on the latest HPV and cervical cancer prevention recommendations and guidelines

Practice Gaps

1. What is the state of cervical screening in the U.S. today?
2. Who are the primary care providers who screen women for cervical cancer prevention?
3. Are primary care providers using HPV testing in primary screening of women 30 and older?
 - a. Private practice
 - b. HMO
 - c. Community Health
 - d. National Breast and Cervical Cancer Early Detection Program
 - e. Planned Parenthood
4. Will it become available in the future?
 - a. Will there be money for HPV testing when there are fewer Pap tests?
 - b. Is there a need to educate administrators of health care settings for women?
5. Are primary care providers following screening guidelines 18 months after publication?

Ways to Overcome and Address Barriers

1. How are primary and women's health care providers learning about new screening and management guidelines now?
 - a. Live meetings
 - b. Webinar
 - c. Publications

2. Which new programs would fill practice gaps?
3. Which organizations might partner to fill in gaps?

Use of “gold standard” HPV and cervical cancer diagnostic tools

Practice Gaps

1. What is the state of HPV screening test in primary care settings today?
2. Are providers, accepting, understanding, and utilizing age-specific practice guidelines and HPV testing?
3. How are primary care providers using HPV testing?
 - a. Substitute for regular cervical cytology screening
 - b. Screening test
 - c. Diagnostic test
4. Will HPV genotyping become the new cervical cancer screening test?
5. As the science of HPV testing increases in specificity and reliability, will the time frame between cervical cancer screenings become longer?

Ways to Overcome and Address Barriers

1. How are we practicing?
 - a. Based on guidelines or patient risk assessment
 - b. Based on potential litigation or guidelines
 - c. Reimbursement/coding
 - d. Lack of knowledge
2. How are we educating the consumers of health (women), providers, and labs?
 - a. Does this look the same?
 - b. Does it occur in silos?
3. Innovative platform for dissemination of new information
 - a. Social media/technology/apps
 - i. Consumers of health

- ii. Providers
- b. Interprofessional information sharing

Implementing HPV and cervical cancer screenings in a variety of clinical settings (e.g., Community Health Centers), given health reform and related policy changes

Practice Gaps

1. Volume purchasing—what are the implications for lab services/tests?
2. How can we use identified gaps/strategies from this morning’s discussion on training for primary care providers to reach/assist Community Health Center providers?
3. What are the cost containment models and evidence to support less frequent screening by more expensive methodology?
 - a. What is the break-even point?
 - b. What can we do about over-screening?
4. State Breast Cancer and Cervical Cancer Early Detection Programs Status?
 - a. Monitoring screening efforts?
 - b. Provider education?
5. Point-of-care enrollment in Medicaid and/or ACA—can we assist Federally Qualified Health Centers to become CAC? Navigators? Champions of Care?
6. Medicaid coverage—all provider types?

Ways to Overcome and Address Barriers

1. What about the consumer side of the equation? Consumer education campaigns targeted at women and the new preventive health package of services
2. Is this happening at the state/local level? Some insured women can’t access this until their plan is considered a “new” plan; Federally Qualified Health Centers will provide this so can we leverage this?
3. Can we identify some win-win partnerships between safety net providers? FP enrollers and Community Health Centers—Easing the anticipated provider shortage for prevention services

Other Issues

- Please consider other issues you feel should be addressed.

Appendix C

Meeting Participants

Expert Clinicians

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Association of Reproductive Health Professionals
Report of the September 20, 2013 Consensus Meeting:
Using New Guidelines to Help Prevent HPV Disease and Cervical Cancer in Women

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Association of Reproductive Health Professionals

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